K070788

OCT 5 ˇ 2007

510(k) Summary - Elecsys Cortisol Test System

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

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Contact person: Kay A. Taylor

Date prepared: September 13, 2007

Device name

Proprietary name:	Elecsys Cortisol Immunoassay Elecsys Cortisol CalSet
Common name:	Cortisol test Calibrator
Classification name:	Cortisol test system Calibrator, Secondary

Device description

(1) The Elecsys Cortisol Assay is a two step competitive immunoassay with streptavidin microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.

(2) The Elecsys Cortisol CalSet is a lyophilized product consisting of human serum with added cortisol (synthetic) in two concentration ranges. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

510(k) Summary - Elecsys Cortisol Test System, Continued

Intended use

(1) Immunoassay for the in vitro quantitative determination of cortisol in human serum, plasma, urine, and saliva. The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.

(2) Elecsys Cortisol CalSet is used for calibrating the quantitative Elecsys Cortisol assay on the Elecsys immunoassay analyzers.

Substantial Equivalence

The Elecsys Cortisol Test System (modified) is substantially equivalent to other devices legally marketed in the United States. The Elecsys Cortisol Test System (modified) is equivalent to the Elecsys Cortisol Test System (K043175).

Device Comparison

The following table compares the Elecsys Cortisol Test System (modified) and the predicate device. The predicate labeling used as the source document for the comparison is that provided to FDA in K043175.

Comparison Table

Feature	Predicate Device Elecsys Cortisol Assay (K043175)	Modified Device Elecsys Cortisol (K070788)
Reagent Intended Use/Indications for Use	Immunoassay for the in vitro quantitative determination of cortisol in human serum, plasma, urine, and saliva. The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.	Same
Calibrator Intended Use	Elecsys Cortisol CalSet is used for calibrating the quantitative Elecsys Cortisol assay on the Elecsys immunoassay analyzers.	Same
Platform(s)	Elecsys 1010, Elecsys 2010, and MODULAR ANALYTICS E170, analyzers.	Elecsys 1010, Elecsys 2010, and MODULAR ANALYTICS E170, **cobas e** 411 and **cobas e** 601 analyzers.
Assay Protocol	Competitive assay	Same

Feature	Predicate Device Elecsys Cortisol Assay (K043175)	Modified Device Elecsys Cortisol (K070788)
Detection	Electrochemiluminescent	Same
Total Assay Duration	18 minute application	Same
Sample Type	Serum, plasma (Li, Na, NH4 Heparin, K2, K3, Na2 EDTA and Na citrate), saliva, urine	Same
Measuring Range	1.00 – 1750 nmol/L or 0.036-63 µg/dL (defined by the lower detection limit and the maximum of the master curve). Values below the detection limit are reported as < 1.0 nmol/L (< 0.036 µg/dL). Values above the measuring range are reported as > 1750 nmol/L (> 63 µg/dL) (or up to 17,500 nmol/L or 630 µg/dL for 10-fold diluted samples).	1.00-1750 nmol/L or 0.036-63.0 µg/dL (defined by the limit of detection and the maximum of the master curve). Values below the limit of blank are reported as < 0.50 nmol/L (< 0.018 µg/dL). Values above the limit of blank but below the limit of detection will not be flagged by the instrument. Values above the measuring range are reported as > 1750 nmol/L (> 63.0 µg/dL) (or up to 17,500 nmol/L or 630 µg/dL for 10-fold diluted samples).
Sensitivity	< 0.500 nmol/L - Analytical (LDL) < 2.0 nmol/L - Functional	≤ 0.5 nmol/L - LoB ≤ 1.0 nmol/L - LoD 8.5 nmol/L - LoQ
Calibrator	Elecsys Cortisol Calset	Elecsys Cortisol CalSet
CalSet Levels	Two	Same
CalSet Matrix	Human serum w/ synthetic cortisol	Same
CalSet Storage	Lyophilized	Same
CalSet Target Conc.	Cal 1: ~12.5 nmol/L Cal 2: ~1000 nmol/L	Same
Traceability / Standardization	Standardized against the Enzymun- Test Cortisol method. This in turn was standardized via ID-MS.	Same

Feature	Predicate Device Elecsys Cortisol Assay (K043175)	Modified Device Elecsys Cortisol (K070788)
Analytical Specificity	For the monoclonal antibodies used, the following cross-reactivities were found: Osteocalcin, PTH fragment 1-37, bone-specific alkaline phosphatase, and β–Crosslaps: no cross-reactivity detectable.	Same – reworded to be more clear No cross-reactivities were found for: Osteocalcin, PTH fragment 1-37, bone-specific alkaline phosphatase, and β–CrossLaps.
Limitations	Limitations remain unchanged from K043175	Same
Reagent Stability	**Unopened:** 2-8°C – Up to the stated expiration date **Opened:** 2-8°C – 12 weeks On the E170/ Elecsys 2010: 8 weeks On the Elecsys 1010: 2 weeks (stored alternately in the refrigerator and on the analyzer-ambient temperature 20-25°C; up to 20 hours opened in total.)	Same – updated for inclusion of cobas e analyzers only
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: E170 and Elecsys 2010: After 1 month (28 days) when using the same reagent lot. After 7 days (when using the same reagent kit on the analyzer). Elecsys 1010: With every reagent kit. After 7 days (20-25°C). After 3 days (25-32°C).	Same – updated for inclusion of cobas e analyzers only

Feature	Predicate Device Elecsys Cortisol Assay (K043175)	Modified Device Elecsys Cortisol (K070788)
Precision	Serum and urine precision data remain unchanged from K043175 **Saliva** **Within-run** 6.1% CV @ 4.68 nmol/L 2.7% CV @ 11.5 nmol/L 4.0% CV @ 15.1 nmol/L 1.5% CV @ 15.9 nmol/L 2.8% CV @ 19.8 nmol/L **Between-run** 37.1% CV @ 0.93 nmol/L 7.2% CV @ 7.72 nmol/L 6.2% CV @ 16.9 nmol/L 4.9% CV @ 34.6 nmol/L 4.1% CV @ 42.5 nmol/L	 **Saliva** **Within-run - SAME** **Between-run** 33.4% CV @ 2.08 nmol/L 11.5% CV @ 8.05 nmol/L 7.1% CV @ 13.1 nmol/L 4.9% CV @ 34.6 nmol/L 4.1% CV @ 42.5 nmol/L
Expected Values	Expected values for serum, plasma, urine remain unchanged from K043175 **Saliva:** The following values were determined in saliva samples from 154 healthy individuals (5^{th} -95^{th} percentile). Morning hours 8-10 a.m: 1.90-19.1 nmol/L (0.07-0.69 µg/dl) Afternoon hours 2:30-3:30 p.m. 2.05-11.9 nmol/L (0.07-0.43 µg/dl)	Same **Saliva:** The following values were determined in saliva samples from 154 healthy individuals (95^{th} percentile). Morning hours 8-10 a.m: <19.1 nmol/L (<0.69 µg/dl) Afternoon hours 2:30-3:30 p.m. <11.9 nmol/L (<0.43 µg/dl)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

Roche Diagnostics, Inc.
c/o Ms. Kay Taylor,
Regulatory Affairs Principal
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Indianapolis, IN 46250-0416

OCT 5 ˇ 2007

Re: k070788
Trade/Device Name: Elecsys Cortisol Immunoassay & Elecsys Cortisol CalSet
Regulation Number: 21 CFR 862.1205
Regulation Name: Cortisol (hydrocortisone and hydroxycorticosterone) test system.
Regulatory Class: Class II
Product Code: NHG, JIT
Dated: September 05, 2007
Received: September 06, 2007

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K070788**

Device Name: **Elecsys Cortisol Test System**

Indications For Use:

Elecsys Cortisol Immunoassay
Immunoassay for the in vitro quantitative determination of cortisol in human serum, plasma, urine, and saliva. The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Elecsys Cortisol CalSet
Elecsys Cortisol CalSet is used for calibrating the quantitative Elecsys Cortisol assay on the Elecsys immunoassay analyzers.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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